

In the Office Action, the pending claims are rejected under 35 U.S.C. §§ 102 and 103 over Taft *et al.*, Drug Metabolism and Disposition, 25(10):1215-1218 (1997) (“Taft”). These rejections are traversed for the reasons set forth below.

I. The Rejection Under 35 U.S.C. § 102 Should be Withdrawn

On pages 2-4 of the Office Action, claims 27-29 and 52-59 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Taft. Applicants respectfully disagree for the following reasons.

It is well settled that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 6312, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in ... [the] claim.” Manual of Patent Examining Procedure (MPEP) § 2131 (8th ed., August 2001); and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The pending claims are directed, in part, to a method of treating an affective disorder in a human, which comprises administering to a human in need of such treatment a therapeutically effective amount of a venlafaxine derivative.¹ In contrast, Taft discloses the administration of venlafaxine itself and the subsequent metabolism of the drug. Taft, page 1. Specifically, Taft discloses the application of a first-pass effect model to characterize the pharmacokinetic disposition of venlafaxine after oral administration to a human, and concludes that “first pass metabolism after oral dosing can be successfully modeled.” *Id.* Taft does not describe the administration of a venlafaxine derivative such as O-desmethyl-venlafaxine (“ODV”) to a human.

It is asserted on page 3 of the Office Action that because ODV is a major metabolite of venlafaxine, “there is no distinction in administering ODV directly or through the parent drug venlafaxine since, in both cases ODV is treating depression.” Applicants respectfully disagree with this unsupported statement. More to the point, however, is the fact that Taft

¹ As recited by dependent claim 57, specific venlafaxine derivatives include (±)-O-desmethylvenlafaxine, (±)-N-desmethylvenlafaxine, (±)-N,O-didesmethylvenlafaxine, and (±)-N,N-didesmethylvenlafaxine.

does not disclose the administration of ODV to a human, *e.g.*, orally as a tablet or capsule (*see* dependent claim 54). Taft simply discloses the formation of ODV *in vivo*.

Because Taft does not disclose each and every element of the claimed invention, Applicants respectfully request that the rejection of claims 27-29 and 52-59 under § 102 be withdrawn.

II. The Rejection Under 35 U.S.C. § 103 Should be Withdrawn

On pages 2-4 of the Office Action, claims 27-29 and 52-59 are rejected under 35 U.S.C. § 103 as allegedly obvious over Taft. This rejection is respectfully traversed.

In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify or combine the cited references, and the prior art references must teach or suggest all the claim limitations. MPEP § 2143. These criteria must be satisfied with factual and objective evidence found in the prior art: an examiner's conclusory statements cannot form a basis for a *prima facie* case of obviousness. *In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002).

As discussed above, the cited art (*i.e.*, Taft) does not disclose all of the limitations of the pending claims. For example, Taft does not disclose the administration of a venlafaxine derivative to a human. Yet the rejection under § 103 is not based on a combination of Taft with any other references. Therefore, because the cited art does not disclose all of the limitations of the pending claims, Applicants respectfully request that the rejection under § 103 be withdrawn. *See* MPEP § 2143.

The Examiner has not cited any art that would have motivated one of ordinary skill to modify Taft in any way, much less in a way that would have yielded the claimed invention.² Consequently, even if one were to assume *arguendo* that Taft did disclose all of the elements of independent claims 27, Applicants respectfully submit that specific elements recited by the claims that depend on it (*e.g.*, claims 28 and 54-59) would not have been obvious to those of ordinary skill in the art. This is an additional reason why the rejection under § 103 should be withdrawn.

² For this reason alone, Applicants respectfully submit that the rejection under § 103 should be withdrawn. *See In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002).

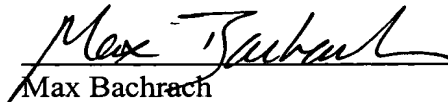
Conclusion

In conclusion, all of the claims are believed to be allowable.

No fee is believed to be due for this submission. However, if any fees are necessary for the entry of this submission or to avoid abandonment of this application, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

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APPENDIX A

Marked-up Version of Amendments

In the Title

Please amend the title as follows: METHODS OF TREATING AFFECTIVE DISORDERS USING DERIVATIVES OF VENLAFAXINE [AND METHODS OF PREPARING AND USING THE SAME]